## REMARKS

### Application Amendments

The Specification has amended to delete material no longer necessary to the present application as replacement figures containing said material has been filed in this case.

Claim 12 has been cancelled, and its limitations have been incorporated into Claim 1. Claims 1 and 4 have been rewritten to more clearly claim the Applicants' invention. Claim 5 has been amended to address the Examiner's rejection under 35 USC §112 and to more clearly claim the Applicants' invention. Claim 19 has been rewritten to more clearly claim the Applicants' invention and in independent form to address the Examiner's objection. Claim 20 has been amended to correct typographical errors and to more clearly claim the Applicants' invention. Support for these amendments may be found throughout Applicants' Specification (for example, at paragraphs [0047], [0052], [0053], [0080], [0094], [0096], [0107], [0113], [0118], [0121] and [0124]) and now cancelled Claim 12. No new matter has been added.

### Claim Rejection under 35 USC §112, First paragraph

Claims 5 stands rejected by the Examiner under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement.

The Examiner asserts that claim 5 is unclear in the use of the term "fibronectin-like blocks", and that the original specification does not provide support for this term.

Applicants have rewritten Claim 5, deleting the term "fibronectin-like blocks". Accordingly, this claim rejection is now obviated.

### Claim Rejections under 35 USC §102

Claims 1, 3-5, 9, 10, 21 and 22 stand rejected by the Examiner under 35 U.S.C. §102 (b) as being anticipated by Buscemi, et al. (US 5,500,013; "Buscemi"). Claims 6, 11-20 stand objected to as being dependent upon a rejected base claim.

According to the Examiner, Buscemi purportedly discloses a device for implanting into the vasculature comprising a biodegradable matrix, at least one drug, and the device having a ring-like structure capable of degrading; drugs for incorporation into the matrix, including anti-inflammatories; mechanical expansion; and, gluing the device to the vessel wall.

Applicants respectfully traverse this rejection as applied to the amended claim set.

Buscemi discloses a biodegradable stent having a tubular body made of a substantially biodegradable matrix essentially saturated with drugs, a plurality of fibers disposed around the body, and a biodegradable strengthening material in contact with the matrix. The drugs are released as the matrix degrades.

Applicants contend that Applicants' Claim 1, as amended, is not anticipated by Buscemi. Applicants' Claim 1 is directed to an implantable device having a ring-like structure, constructed to degrade gradually until complete degradation, and comprising a biodegradable matrix material capable of dissolving upon contact with blood, one or more particles incorporated into the biodegradable matrix material, and, at least one drug coated onto or incorporated into the one or more particles and capable of being released into the blood stream as the biodegradable matrix material dissolves. Applicants submit that Buscemi does not teach the incorporation of one or more particles into the biodegradable matrix material. Buscemi's disclosures that "a plurality of microcapsules that are dispersed in the biodegradable material. The microcapsules contain a material that induces crosslinking of the biodegradable material" (at col. 7, lines 38-45, and similarly at col. 9, lines 11-17) and "drugs are included within microcapsules" (at col. 10, lines 61-62) do not equate to the particles of the present invention. According to The American Heritage® Dictionary of the English Language, 4th Ed.*(Published by Houghton Mifflin Company.* © 2006 by Houghton Mifflin Company), a particle is defined as "a very small piece or part; a tiny portion or speck", such as a very small piece of solid matter, while a microcapsule is defined as "a small, sometimes microscopic capsule designed to release its contents when broken by pressure, dissolved, or melted", with capsule being defined as "small soluble container, usually made of gelatin, that encloses a dose of a medicine or a vitamin". This is confirmed by Buscemi, at col. 9, lines 14-17, by "mechanical energy is applied to the tubular main body in order to burst the microcapsules". While the Applicants' particles comprise iron oxide ($Fe_3O_4$), titanium, titanium alloy, titaniumoxide ($TiO_2$), magnesium oxide, palladium oxide, palladiumcobalt, bioceramic, bioglass, resin, cement, hydroxyapatite, calcium sulfate, aluminum oxide ($Al_2O_3$), tricalcium phosphate, calcium phosphate salt, carbon, cobalt-based alloy, titanium-based alloy, zirconium oxide, zirconia, aluminum-based alloy, vanadium-based alloys, molybdenum-based alloy, nickel-based alloy, iron-based alloy, zinc-based alloy, zinc phosphate, zinc polycarboxylate, epoxy, polyester, acrylic, nylon, silicone, polyanhydride, polyurethane,

polylactide poly(L-lactide), poly(D-lactidepoly), copolymer derived therefrom polylactide poly(L-lactide) or poly(D-lactidepoly), polycarbonate, poly(tetrafluoroethylene), polycaprolactone, polyethylene oxide, polyethylene glycol, poly(vinyl chloride), polyglycolic acid, polypropylene oxide, poly(akylene)glycol, polyoxyethylene, sebacic acid, polyvinyl alcohol, 2-hydroxyethyl methacrylate, polymethyl methacrylate, 1,3-bis(carboxyphenoxy)propane, phosphatidylcholine, triglyceride, polyhydroxybutyrate, polyhydroxyvalerate, poly(ethylene oxide), poly ortho ester, poly (amino acid), polycynoacrylate, polyphophazene, polysulfone, polyamine, poly (amido amine), siloxane-based elastomer, siloxane-based elastomer comprising 3,3,3-trifluoropropyl groups, lipid, isopropyl styrene, flexible fluoropolymer, vinyl pyrrolidone, cellulose acetate dibutyrate, silicone rubber, hydroxapatite, fibrin, graphite, manganese-lithium alloy comprising from about 0.5 wt % to about 20 wt % of lithium, or any combination thereof (hereinafter "Applicants' particle composition"), Buscemi's microcapsules are merely containers that carry crosslinking material or drugs. Clearly, Buscemi's microcapsules are nothing like the particles of the present invention.

Therefore, Buscemi does not disclose an implantable biodegradable device comprising one or more particles and at least one drug coated onto or incorporated into the one or more particles, said one or more particles comprising Applicants' particle composition and being incorporated into the biodegradable matrix. Therefore, Applicants submit that all of the elements of Applicants' amended Claim 1 are not found in Buscemi.

Applicants contend that the device of the present invention differs from Buscemi's stent in its design. As stated in the Applicants' specification (at paragraph [0094] of the published application), the implantable device having a ring-like structure of the present invention differs from a stent in that the stent requires more mechanical strength to push against the vessel wall as the stent has to hold open the vessel, while the present device only has to clamp itself against the vessel wall to stay in place. This is confirmed by Buscemi, at col. 4, lines 14-15, by "the stent strengthens an area of the vessel that is in contact with the stent" and, at col. 7, lines 50-52, by "crosslinking the biodegradable material imparts a strength to the stent sufficient to hold open the lumen". The purpose of a stent is to hold the vessel open by mechanical strength to prevent the vessel from occlusion, while the purpose of the present device is to stay in place and release a drug. Although the present device may be as long as a stent or shaped exactly like a stent, the

two devices serve different purposes. Because a stent in general has to hold the vessel open over a longer distance of space and a longer duration of time, the stent must be constructed in such a way that it sustains more mechanical force. Because the present device has to only carry a drug to be released into the blood stream or to the vessel wall itself, and to dissolve and vanish thereafter, it does not need to be constructed to sustain a mechanical force of the magnitude required for a stent.

Applicants submit that as independent Claim 1 is non-anticipated, rejected Claims 3-5, 9, 10, 21 and 22 and objected to Claims 6, 11, and 13-18, depending from and thus incorporating all elements of independent Claim 1, are also non-anticipated and therefore allowable [*In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)]. Claim 19 has been rewritten in independent form; thus, the Examiner's objection to Claims 19 and 20 is now obviated. Claims 19 and 20, as rewritten, are now allowable.

Accordingly, Applicants submit that the Applicants' amended Claim 1, and claims depending therefrom, are patentable over Buscemi for the reasons stated above. It is respectfully submitted that amended base Claims 1 and 19 and their dependent Claims 3-6, 9-10 and 13-22 are now in condition for allowance and that the Examiner's rejection and objection should be withdrawn.

## CONCLUSION

For all of the foregoing reasons, it is respectfully submitted that amended Claims 1, 3-6, 9-10 and 13-22 are in condition for final allowance. Notice to such effect is respectfully requested.

No fees are believed to be due by the present amendments.

Should the Examiner have any questions or requires any additional information from Applicants' attorney, the Examiner is invited to contact the undersigned.

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Respectfully submitted,

*Lucy Elandjian*

By: _____
Lucy Elandjian
Reg. No. 46,164

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IP Law Services, LLC
PO Box 4557
Edwards, CO 81632
(617) 948-9772
lelandjian@iplawservices.com